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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,275	07/08/2003	Wei-Wu He	PF219D1	7739

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EXAMINER	
BRISTOL, LYNN ANNE	
ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
05/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/614,275	HE ET AL.	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45 and 48-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-45 and 48-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/20/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-45 and 48-64 are all the pending claims for this application.

2. Claims 23, 34, 45, 54, 63 and 64 have been amended in the Response of 3/20/07. The amendment of Claims 23, 34, 45 and 54 raises a new matter issue as discussed infra.

3. Claims 1-45 and 48-64 are all the pending claims under examination.

4. Applicants amendments to the claims have necessitated new grounds for rejection. This action is **FINAL**.

Information Disclosure Statement

5. The non-patent literature reference cited in the IDS of 3/20/07 has been considered and entered.

Objections Maintained

Specification

6. The objection to the specification for the improper use of trademarks is maintained. The use of the trademark, rediprime™, is improper. Applicants are invited to verify the trademark through the Amersham website. Applicant's allegations on p. 8 of the Response of 3/20/07 are acknowledged.

Applicants are advised to carefully check the specification for any other trademarks that are not properly identified.

Withdrawal of Rejections

Claims - 35 USC § 101/112, first paragraph

7. The rejection of Claims 1-45 and 48-64 under 35 U.S.C. 101 as not being not supported by either a substantial asserted utility or a well established utility/enabled is withdrawn.

Applicant's allegations on pp. 8-16 of the Response of 3/20/07 have been considered in further view of the Steadman et al. reference, and are found to be persuasive. Steadman discloses that NKX3.1 protein acts as transcriptional repressor for a luciferase reporter gene construct in vitro.

The Examiner submits that a post-filing date reference by another author showing a function (as accurately predicted in applicant's specification, i.e., transcriptional gene regulation) for the same protein (NKX3.1) is sufficient to overcome the rejection.

Rejections Maintained

Claims - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Biological Deposit Requirements

8. The rejection of Claims 12-22, 34-44 and 54-62 under 35 U.S.C. § 112, first paragraph, for failing to comply with the requirements for a biological deposit under the

terms of the Budapest Treaty is maintained.

Applicant's allegations on pp. 16-17 of the Response of 3/20/07 and the attachments enclosed under Exhibit B have been considered but are not found persuasive. Applicants allege that the instant specification contains the correct deposit information with the ATCC for two deposits designated "209005" and "209006" in the specification on p. 7. However, in the attachment under Exhibit B, the copy of "p. 7" from a specification describes the deposited material for each of the accession numbers as being the opposite of what is disclosed in the instant specification. On pp. 6-7 of the instant specification, the genomic clone (NKX3.1; SEQ ID NO:8) is identified as accession no. 209005, and the nucleotide sequence for the HPFCA19 clone (SEQ ID NO: 1 or 3) is identified as accession no. 209006. Significantly, the copy of "p.7" discloses that the HPFCA19 clone (SEQ ID NO: 1 or 3) is identified as accession no. 209005 while the genomic clone (SEQ ID NO:8) is identified as accession no. 209006. The copy of the ATCC receipt under Exhibit B describes two deposits as DNA plasmids: NKX3.1 and HPFCA19. Finally, Applicants "statement of assurance", which is not present in the originally filed specification, but provided on p. 16 of the Response of 3/20/07, does not indicate what material corresponds to which deposit number.

Applicants are required to address the conflicting information and to provide further corroborating evidence that the deposited materials are consistent with the disclosures in the specification and the claimed deposit numbers.

Written Description Requirements

9. The rejection of Claims 23-45 and 48-62 under 35 U.S.C. 112, first paragraph, as drawn to polypeptides comprising contiguous regions of 30 or 50 amino acid residues of SEQ ID NO:2 or 4 or from a full-length protein encoded by DNA of ATCC deposit No. 209005 or 209006, or having at least 95% sequence identity to amino acid residues 1-234 of SEQ ID NO:2 or from a full-length protein encoded by DNA of ATCC deposit No. 209005 or 209006 is maintained for reasons of record set forth in the Office Action of 9/20/06.

Applicants allege on pp. 17-20 numerous cited case law holdings support the position that the mere description or contemplation of protein variants and fragments for proteins of SEQ ID NO:2 or 4 is sufficient to place an applicant in possession of the invention. Applicants further allege that one skilled in the art "could readily envision countless polypeptide sequences that comprise the specified polypeptides" (p. 19, ¶3).

Applicants arguments and legal analysis do not replace what Applicants were never in possession at the time of filing- which is simply a single working example of a NKX3.1 protein variant or any claimed portion of the NKX3.1 protein showing its function as a transcriptional regulator of any gene much less a prostate-specific gene. Just because Applicants possessed the gene and protein sequence for NKX3.1, they have not demonstrated they were also in possession of the myriad protein fragments encompassed by the claims or that all of the embodiments would be functional transcriptional regulators. Thus Applicants cannot rely on the specification for showing a materially relevant function for the NKX3.1 proteins.

Further, Applicants could not even rely on the Steadman et al. reference alone (or in combination with the specification) as showing possession, because Steadman only shows transcriptional regulation of an artificial construct by the NKX3.1 protein comprising the gene (luciferase) and occurring thru an artificial promoter (thymidine kinase) under *in vitro* conditions. Neither the specification alone or in combination with Steadman meets all of the limitations for the claims, namely that the myriad protein fragments act as transcriptional regulators in prostate tissue. Where in the specification have Applicants demonstrated that the myriad protein fragments actually regulate transcription for any gene much less in a prostate tissue? ("An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formulas that fully set forth the claimed invention" *Lockwood v. American Airlines, Inc.* 107 F.3d 1565, 1572 (Fed. Cir. 1997)); MPEP 2163).

Enablement Requirements

10. The rejection of Claims 1-45 and 48-64 under 35 U.S.C. 112, first paragraph, as not being enabled for enabled for making or using a full-length human (or murine) NKX3.1 protein of SEQ ID NO:2 or 4 or a full length NKX3.1 protein encoded by genomic DNA or cDNA of ATCC Deposit No.209005 and 209006 or proteins having at least 95 % identity with the protein of SEQ ID NO:2 or 4 or peptides comprising 30 or 50 contiguous amino acids of SEQ ID NO:2 or 4 is maintained for reasons of record set forth in the Office Action of 9/20/06.

Applicants allege on pp. 20-27 that they are no burden to demonstrate that 1) a full length NKX3.1 protein can be successfully and reproducibly expressed in a bacterial cell much less any other host cell (see p. 22, ¶2), 2) the mRNA and protein expression levels are correlative for NKX3.1 because "the lack of at least some general correspondence is the exception rather than the rule" with respect to mRNA and proteins in general (see p. 24, ¶2), and 3) any NKX3.1 variant can be produced and would have biological activity based on the guidance in the specification (see p. 26, ¶4).

The Examiner submits that based on the absence of any functional examples for the NKX3.1 protein and variants thereof, and Applicants apparent unwillingness to supplement the record with experimental data supporting the instant claim scope, that Applicants have not met their burden in establishing enablement. Applicants cannot rely on the Steadman reference as an enabling disclosure for a functional NXK3.1 protein because the effect of the protein as a transcriptional regulatory for any biologically relevant gene in vivo much less a gene in a prostate tissue is not nearly established by Steadman. Neither the specification nor Steadman teach an example of an in vitro model that has correlative meaning for the NKX3.1 protein having a biologically relevant transcription regulatory property in any tissue or a prostate tissue. (MPEP 2164.02 "Correlation: In Vitro/ In Vivo).

Claims - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. The rejection of Claim 64 under 35 U.S.C. 102(a) as being anticipated by Sciavolino et al. (Developmental Dynamics 209:127-138 (May 1997)) is maintained for reasons of record set forth in the Office Action of 9/20/06.

Applicant's allegations on p. 27 of the Response of 3/20/07 and the 1.131 Declaration of Drs. Carter and He have been considered but are not persuasive. Applicants have not met their burden (formal requirement) in antedating the Sciavolino reference with the Declaration and Exhibit A and B attachments, because the Declaration has not been executed by Dr. He. Pursuant to 37 C.F.R. 1.131 a declaration must be signed by the inventors of at least the subject matter of the claims under rejection unless unavailable, in which case another party of interest must sign (legal representative or assignee where appropriate).

12. The rejection of Claim 64 under 35 U.S.C. 102(a) (*formerly 102(b)*) as being anticipated by Bieberich et al. (J. Biol. Chem. 271:31779-31782 (December 13, 1996)) is maintained for reasons of record set forth in the Office Action of 9/20/06.

Applicant's allegations on p. 28 of the Response of 3/20/07 and the 1.131 Declaration of Drs. Carter and He have been considered but are not persuasive.

The Examiner has verified that SEQ ID NOS: 1 and 2 have priority in U.S. Provisional Application NO. 60/051,080 (6/27/97), thus the Bieberich reference is a 102(a) reference as against Claim 64.

However, Applicants have not met their burden (formal requirement) in antedating the Bieberich reference with the Declaration and Exhibit A and B attachments because the Declaration is not executed by Dr. He. Pursuant to 37 C.F.R. 1.131 a declaration must be signed by the inventors of at least the subject matter of the claims under rejection unless unavailable, in which case another party of interest must sign (legal representative or assignee where appropriate).

New Grounds for Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 23-45 and 48-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claims 23-45 and 48-62 are indefinite for the recitation "wherein the isolated polypeptide regulates transcription in prostate tissue" in Claims 23, 33, 43 and 54 because it is not clear which of any genes in a prostate tissue is being transcriptionally regulated. The claim reads on any known or yet to be discovered gene that is transcriptionally regulatable through NKX3.1.

Conclusion

14. No claims are allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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